

IN THE SPECIFICATION:

Please replace paragraph number [0027] with the following replacement paragraph:

[0027] FIGS. 3A to ~~3G~~ 3H are plan views of different aspects of interactions between a catheter hub and a support hub, in accordance with the present invention.

Please replace paragraph number [0032] with the following replacement paragraph:

[0032] The innermost component of the assembly is preferably fashioned as a solid central stylet 17. When inserted in the support needle 19 (discussed in detail further herein), the central stylet 17 prevents the entry of extraneous tissue or other material into the support needle opening 28 during insertion. The central stylet may also serve as a “stiffening” portion of the assembly providing extra support and stiffness to the entire assembly. The hub 25 of the central stylet 17 is outermost, or located at an extreme proximal end 26 of assembly 10, because the central stylet 17 is the first to be removed. An attachment structure, such as tab 34, may be located on the hub 25 for retaining the central stylet 17 in the support needle ~~25~~ 19. The tab 34 may interact with a corresponding attachment structure on the hub 35 of the support needle ~~19~~, 19.

Please replace paragraph number [0035] with the following replacement paragraph:

[0035] The central stylet 17 may be attachable to the support needle 19, as illustrated in FIGS. 1 & 2. The central hub 25 typically carries an attach structure, such as tab 32, to interface in a structural interference with an attach structure 34 carried by support hub 35. As illustrated, ~~attach structure~~ tab 32 and attach structure 34 cooperatively form a slidably engageable joint. Alternative releasable retaining joint configurations, including rotatable attachments such as LUER-LOCK® type joints, may also be used.

Please replace paragraph number [0036] with the following replacement paragraph:

[0036] The outermost layer of the assembly 10 is the catheter 15 itself. It preferably is approximately 23g and about the length of a conventional spinal needle, although different diameters and lengths for use with different procedures is within the scope of the present ~~invention~~ invention. Conventional plastic catheter material may be used in its construction. The catheter material may be reinforced with a flat ribbon internal spring 45 (shown in FIG. 5), an internal or external wire wrap, or other reinforcing structure. Alternative materials, and various materials in combination, also may be used to construct a catheter 15. Suitable catheter material produces a catheter 15 which is fairly stiff and has a sufficiently high tensile strength to maintain structural integrity during insertion, while in the body, and during retraction from a patient. A catheter 15 desirably possesses sufficient transverse flexibility to deform and accommodate patient motion to reduce irritation from the presence of a foreign body.

Please replace paragraph number [0040] with the following replacement paragraph:

[0040] It is desirable to prevent inadvertent premature removal of the support needle 19 from the catheter 15. In the embodiment depicted in ~~FIGS~~ FIGS. 1-3, support hub 35 receives thread structure 37 located on the catheter hub 39 and locks with rotation. Such a positive connection may be desirable and can form a LUER-LOCK® or other rotatable-type joint. Other such interlocking or even alternative retaining structure may also be used. For example, a secure friction fit attachment between support needle 19 and catheter 15 is within contemplation in the practice of this invention, as is a structural interference fit of attachment structures similar to shown in connection with tab 32 on the central stylet 17.

Please replace paragraph number [0042] with the following replacement paragraph:

[0042] FIG. 3B depicts a somewhat similar arrangement where a retaining lever 40B is rotatably attached to the support hub 35B and includes an enlarged distal end 44B with a lip that forms a structural interference fit with an ~~attach-structure,~~ structure, such as distal end 50B of the catheter hub 39B. Additionally, retaining lever ~~49B~~ 40B includes a detach assisting structure, such as detach bar 48B that resides between the catheter hub 39B and the support hub 35B in the retained-~~positioned~~ position. When proximal end 46B of the retaining lever 40B is ~~depressed~~ depressed, distal end 44B rotates out from the catheter hub 39A releasing it. Simultaneously, detach bar 48B presses against the proximal end of the catheter hub 39B, causing support needle 19B to begin withdrawing from catheter 15B. It will be appreciated that although only one retaining lever 40B is shown for clarity, any desired number of retaining levers 40B may be used. Further, although a pin hinge 42B is depicted, any suitable rotatable connection, such as a living hinge formed from injection molded plastic, may be used.

Please replace paragraph number [0044] with the following replacement paragraph:

[0044] Another example of aspects of a detach assisting structure is depicted in FIG. 3D. A detach lever 52D is rotatably ~~attached~~ attached to catheter hub 39D through a pin hinge 54D or another flexible connection. The attachment may occur on a protrusion, or detachment extension 51D, extending out from the catheter hub 39D body. Detach lever 52D has a detaching end 56D that resides between the catheter hub 39D and the support hub 35D when the hubs are in the retained position. The opposite actuation end 58D of the detach lever ~~40B~~ 52D may include a grip area formed ~~as~~ as a roughened surface. Detach lever 52D is actuated by pressing the actuation end 58D in the distal direction causing the detaching end ~~54D~~ 56D to rotate out from the catheter hub 39D

pressing against the distal end of the support hub 35D, causing support needle 19D (not shown) to begin withdrawing from catheter 15D.

Please replace paragraph number [0046] with the following replacement paragraph:

[0046] FIG. 3F depicts a catheter hub 39F including an enlarged bore opening 50F and a support hub 35F having a relationship similar to that described with respect to FIG. 3E. Additional retention structures are also depicted. Support hub 35F includes a lip 40F extending distally ~~from~~ from the hub body to create a recess 41F. Lip 40F includes an enlarged distal end 42F and may be resilient. As the needle 19F is inserted into catheter 15F and a portion of the support hub 35F is inserted into enlarged bore opening 50F, lip 40F passes over a portion of the catheter hub 39F, flexing outward to allow enlarged distal end 42F to pass over a ridge 52F on the catheter hub 39F. Enlarged distal end 42F blockably interacts with ridge 52F to prevent inadvertent removal of the needle 19F. At the appropriate point in the procedure, the hubs may be separated by applying sufficient force to the hubs in opposite directions to cause the lip 40F to flex and allow the enlarged ~~ends~~ distal end 42F to pass over the ridge 52F. Grip points 50F and 44F may be provided on the catheter hub 39F and support hub 35F, respectively, to assist in the removal of the needle 19F. It will be appreciated that lip 40F may be formed as an ~~extensions~~ extension around the entire circumference of the support hub 35F taking the shape thereof, whether generally circular or otherwise, or may be formed as a plurality of separate extensions, and all such embodiments are within the scope of the present invention.

Please replace paragraph number [0047] with the following replacement paragraph:

[0047] FIGS. 3G and 3H depict a rotatable retaining relationship between catheter hub 39G and support hub 35G. Support hub ~~35-G~~ 35G includes a number of discrete protrusions, such as retaining tabs 40G at a point along the hub body. Catheter hub 39G

includes ~~a~~ an enlarged bore opening 50G into which a portion of the body of the support hub 35G may be inserted. The mouth 52G of enlarged bore opening 50G is best depicted in ~~FIG~~FIG. 3H. A central section of mouth 52G allows the support hub 35G body to pass therethrough, yet is too small to allow the tabs 40G to similarly pass. Mouth 52G includes bays 53G extending into the proximal end of the catheter hub 39G from the central section of the mouth 52G. Each bay 53G corresponds to a tab 40G and allows passage therethrough to the enlarged bore opening.

Please replace paragraph number [0049] with the following replacement paragraph:

[0049] As best shown in FIG. 3, catheter 15 may include a flexible kink sleeve 18. ~~Kink-sleeve~~ sleeve 18 covers a portion of the proximal surface of the catheter 15 to protect the area covered against kinking and damage during bending. Desirably, the kink sleeve 18 will begin at the base of the catheter 15 inside the hub 39 (as depicted in FIG. 3) to provide maximum protection, although alternate embodiments where kink sleeve begins distal to the base of the catheter inside the hub 39, or at the base of the hub 39 are within the scope of the present invention. Kink sleeve 18 may extend distally along the length of the catheter 15 to a length appropriate for the planned use of the catheter. Typically, kink sleeve 18 will extend to a length sufficient to prevent kinking of the catheter at the skin of the patient or within the skin and fascia of the patient. Kink sleeve 18 may be constructed of any suitable flexible material that is medically acceptable, including polymers such as nylon.

Please replace paragraph number [0050] with the following replacement paragraph:

[0050] When catheter 15 is fully inserted, a portion of the kink sleeve 18 will reside within the skin and fascia of the patient. The hub 39 may then be bent over and taped to the skin, if desired. The kink sleeve 18 acts to protect the catheter 15 during this bending process, which may bend the catheter 15 at an angle of about 90 degrees or more.

The kink sleeve 18 absorbs the force of the bend and maintains the catheter 15 in a position allowing flow therethrough. Kinking of the catheter 15 is thus minimized, and may be prevented. The kink sleeve 18 may be impregnated, coated, or otherwise treated with a biocompatible infection resistant ~~substance~~to substance to prevent adverse tissue reaction or infection at the catheter entry site. Embodiments where the catheter hub 139 (FIG. 4) lies flat against the skin, allowing attachment at ~~a~~an angle generally perpendicular to insertion may further avoid potential kinking. Similar to kink sleeve 18, the catheter hub 139 may be impregnated, coated, or otherwise treated with a biocompatible infection resistant ~~substance~~to substance to prevent adverse tissue reaction or infection at the catheter entry site.

Please replace paragraph number [0052] with the following replacement paragraph:

[0052] Connection outlet 110 may include a connection structure, such as the LUER-LOCK® type threads 112 depicted in FIG. 4, in order to allow tubing, a connection line, a syringe or other structure to be attached thereto in communication with connection bore 116 and bore 114. A line connected to connection outlet ~~114~~110 may lay flat on the skin of a patient resulting in a more comfortable connection than a perpendicular connection.

Please replace paragraph number [0053] with the following replacement paragraph:

[0053] Similarly, alignment opening 120 may include a connection structure, such as LUER-LOCK® type threads, in order to allow tubing, a connection line, a syringe or other structure to be attached thereto in communication with bore 114. Upon withdrawal of the support needle 19 after catheter 15 placement, alignment ~~opening~~opening 120 may be closed by capping, with a cap or an injectable port (to provide another point for the introduction of suitable treatment solutions to the catheter 15). In some embodiments, a resealable puncturable membrane may be provided across the alignment opening 120 (or

the bore 114 above connection bore 116) to allow insertion of a support needle and central stylet therethrough, while sealing the bore 114 upon their removal.

Please replace paragraph number [0056] with the following replacement paragraph:

[0056] Once CSF is observed at the hub 35 of the support needle 19, the clinician can be certain that the tip 29 of the catheter 15 is within the intrathecal space. If desirable for the procedure, the clinician may continue to advance the hollow—~~stylet~~ needle/catheter 19/15 assembly another centimeter or so. At this point, the hub 35 of the hollow—~~stylet~~ needle 19 is typically twisted to unlock it from the catheter hub 39 or 139, and while holding the hollow—~~stylet~~ needle 19 stationary, the catheter 15 is advanced all the way until the hub 39 or 139 contacts the patient's skin. For embodiments including a kink sleeve 18, this advancement inserts, or further inserts, the kink sleeve 18 within the patient's skin.

Please replace paragraph number [0057] with the following replacement paragraph:

[0057] At this point, the hollow support needle 19 may be removed, and the appearance of CSF at the catheter hub 39 or 139 will confirm the correct placement of the catheter 15. The desired injection port, tubing, or other medical fluid transfer apparatus, may then be attached to the catheter hub 39 (or 139) such as by way of ~~attach~~ thread structure 37 (or threads 112). Where necessary, the catheter 15 may be bent and taped to the patient's skin before—~~of~~ or after the attachment of the corresponding apparatus, if required. Where included, kink sleeve 18 protects the catheter 15 from kinking and damage at the bend. A piece of slotted, circular foam tape (which might also be treated with an antimicrobial) may also be applied to fix the hub 39 or 139 to the skin, prevent dislodging of the catheter 15, and cushion the patient to reduce potential irritation from the hub 39 or 139.